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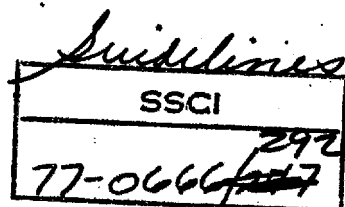
National Commission for the Protection of Human Subjects  
of Biomedical and Behavioral Research

Westwood Building, Room 125  
5333 Westbard Avenue  
Bethesda, Maryland 20016

August 23, 1977

OLC #77- 4278

Mr. Walter Elder  
Executive Secretary  
National Foreign Intelligence Board  
Intelligence Community Staff  
Washington, D.C. 20505



Dear Mr. Elder:

On June 10, 1977, the Commission reviewed revised draft "Guidelines for Human Subject Research Within the Intelligence Community" and attachments thereto which you forwarded to us for comment. Some Commission members expressed concern regarding classified research conducted or supported by the Intelligence Community, and they requested clarification from your staff before commenting on the draft. On July 8, Lt. Col. Arkadie Novickoff and Dr. Salvatore Cianci testified before the Commission, explaining the nature of research conducted or supported by the Intelligence Community and the purpose of classifying some of such research as secret. Following consideration of this testimony, as well as a review of the proposed directive, the Commission offers the following comments on the draft "Guidelines."

The revised directive is a clear improvement over the first draft (dated 16 December 1976) and reflects most of the previous comments of this Commission. We appreciate the care with which your staff has responded. Our primary remaining concern is one that cannot be disposed of within the Intelligence Community itself, but would require presidential action, at a minimum, or legislation. Specifically, the Commission is concerned with the need to provide strong assurance that human rights will be protected in classified research. The mere promulgation of a directive such as the "Guidelines" may clarify the basic policies that the various intelligence agencies are expected to follow, but carries little force or authority beyond that of exhortation. Adherence to the basic policies should be required at least by Executive Order. Preferably, deviation from such policies as are established in the "Guidelines" should be prohibited by statute. Only if such steps are taken can we be reasonably assured that the well-intentioned "Guidelines" will in fact be followed by the intelligence agencies.

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Our suggestions for specific modification of the "Guidelines" are as follows:

(1) When sponsorship of research is not to be disclosed for security considerations, the "Guidelines" should require that subjects be informed, as part of the information provided when their consent is solicited, that the sponsor does not wish to be identified. ✓

(2) In the rare instances in which all aspects of a research project are classified and the research, therefore, must be reviewed by an Institutional Review Board (IRB) of which all members have security clearance, a second review of the protocol should be required. Preferably, such review would be performed by this Commission or its successor body; alternatively, it could be accomplished by the select committees in Congress having oversight of Intelligence Community operations. This would strengthen monitoring of the Intelligence Community's research activities, and, secondarily, enhance public confidence. ?

(3) The duties of the "resident expert," as described in Section 5(b), should be expanded to include review of the composition and operations of IRBs reviewing Intelligence Community research, when such IRBs do not have approved assurances on file with DHEW. In addition, the "resident expert" should be designated, at least for intramural research, as a person to be contacted by subjects in the event of adverse effects attributable to participation in research.

(4) The "Guidelines" should require the maintenance by appropriate authorities of records identifying subjects of drug research or other research presenting risk of harm that may not become known until after the research has been conducted. This would enable subjects to be contacted for follow-up examinations and would facilitate corroboration of claims of research-related injury.

We appreciate your openness and cooperation in developing this directive and your sensitivity to the problems of protecting human subjects. The "Guidelines" are, with the few exceptions noted above, a fine example of protective requirements; our major concern, as I have indicated, is the absence of clear authority to require compliance. We shall transmit this concern directly to the President and the appropriate Congressional committees, since we appreciate the fact that it is not within your authority to respond to them.

Thank you for the opportunity to review and comment on the draft "Guidelines"; your staff should be complimented for a fine job.

Sincerely yours,

